



IFW

Docket No.: 3691-0133PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Takashi NISHIMURA et al.

Application No.: 10/583,860

Confirmation No.: N/A

Filed: June 21, 2006

Art Unit: Not Yet Assigned

For: **PROCESS FOR PRODUCING ENGINEERED
TARGETED T CELL AND MEDICINE**

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

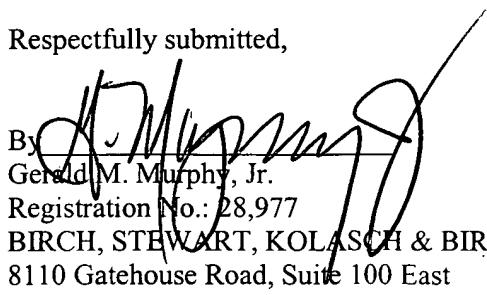
Sir:

Subsequent to the filing of the above-identified application on June 21, 2006, attached hereto is an English Translation of the International Preliminary Report on Patentability issued by the International Bureau on behalf of the International Searching Authority. Please make this document of record for the above-identified application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: September 25, 2006

Respectfully submitted,

By 
Gerald M. Murphy, Jr.
Registration No.: 28,977
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road, Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicant

Attachment

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

Date of mailing (day/month/year)
31 August 2006 (31.08.2006)

To:

OHNO, Seiji
OHNO & PARTNERS, Kasumigaseki Building 36F, 2-5,
Kasumigaseki 3-chome, Chiyoda-ku, Tokyo
1006036
JAPON



Applicant's or agent's file reference PHT-9002WO	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/019714	International filing date (day/month/year) 22 December 2004 (22.12.2004)
Applicant HOKKAIDO TECHNOLOGY LICENSING OFFICE CO., LTD. et al	

1. Transmittal of the translation to the applicant.

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

Facsimile No. +41 22 338 82 70

Facsimile No. +41 22 338 82 70

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PHT-9002WO	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2004/019714	International filing date (<i>day/month/year</i>) 22 December 2004 (22.12.2004)	Priority date (<i>day/month/year</i>) 22 December 2003 (22.12.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant HOKKAIDO TECHNOLOGY LICENSING OFFICE CO., LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input type="checkbox"/> Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

	Date of issuance of this report 22 August 2006 (22.08.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

TRANSLATION
PCT

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.1)

		Date of mailing (day/month/year)
Applicant's or agent's file reference PHT-9002WO		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/JP2004/019714	International filing date (day/month/year) 22.12.2004	Priority date (day/month/year) 22.12.2003
International Patent Classification (IPC) or both national classification and IPC		
Applicant HOKKAIDO TECHNOLOGY LICENSING OFFICE CO., LTD.		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/019714

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 in written format
 in computer readable form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/019714

Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application

claims Nos. 20-21

because:

the said international application, or the said claims Nos. 20-21

relate to the following subject matter which does not require an international preliminary examination (*specify*):

The inventions of Claims 20-21 relate to a method for treatment or diagnosis of the human body, which does not require an examination by the International Examining Authority in accordance with Patent Cooperation Treaty Article 17(2)(a)(i) and Rule 39.1(iv) based on the Patent Cooperation Treaty.

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. 20-21

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

has not been furnished

does not comply with the standard

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.	PCT / JP2004 / 019714
-------------------------------	-----------------------

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																			
<p>1. Statement</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Novelty (N)</td> <td style="width: 60%;">Claims <u>1-19</u></td> <td style="width: 20%;">YES</td> </tr> <tr> <td></td> <td>Claims _____</td> <td>NO</td> </tr> <tr> <td>Inventive step (IS)</td> <td>Claims _____</td> <td>YES</td> </tr> <tr> <td></td> <td>Claims <u>1-19</u></td> <td>NO</td> </tr> <tr> <td>Industrial applicability (IA)</td> <td>Claims <u>1-19</u></td> <td>YES</td> </tr> <tr> <td></td> <td>Claims _____</td> <td>NO</td> </tr> </table> <p>2. Citations and explanations:</p> <p>Document 1: Igaku no Ayumi (2000), Vol. 195, No. 1, pp. 3-8 Document 2: Cancer therapy & host (2000), Vol. 12, No. 4, pp. 363-373 Document 3: Clinical Immunology (2002), Vol. 38, No. 4, pp. 363-369 Document 4: Igaku no Ayumi (2002), Vol. 200, No. 6, pp. 481-486 Document 5: Monbusho Kagakukenshō Hojokin ni yoru gan-juten kenkyu-hokokushu roku: Gan-kenkyuu ni kakaruto juten-ryoiki kenkyu (Gan-juten) (1997), pp. 525-528 Document 6: Hematology & Oncology (1999), Vol. 38, No. 1, pp. 22-29 Document 7: J. Immunol. (1996), Vol. 156, pp. 3159-3165</p> <p>Claims 1-19 The inventions of Claims 1-19 do not appear to involve an inventive step over the inventions described in documents 1-7. Documents 1-4 describe as issues a process of inducing Th1 cells having anti-tumor activity, and their use in cancer-specific immunotherapy. The inventions described in documents 1-4 differ from the inventions of Claims 1-4 of this application in that they do not describe, as a process for providing antigen specificity, the introduction of a gene for a TCR which recognizes a cancer-associated antigen. However, documents 5-6 describe preparing cancer-specific cytotoxic T cells by introducing a gene for a cancer-specific T cell antigen receptor. Consequently, a person skilled in the art could easily conceive of manufacturing cells for cell therapy by introducing a gene for a TCR which recognizes a cancer-associated antigen described in document 5-6 into Th1 cells having anti-tumor activity to resolve the issues described in documents 1-4. Moreover, since it is not particularly difficult to select a publicly known cancer-associated antigen, the same applies to the invention of Claim 5. The same also applies to the invention of Claim 6 since induction with anti-CD3 antibodies and IL-2 and -12 is described in document 7. The same also applies to the inventions of Claims 7-8 since methods of preparing cells using beads or the like are merely well known technique. Moreover, since documents 5-6 relate to Tc cells and simultaneously providing antigen specificity to Tc cells is a matter that can be accomplished as appropriate, the inventions of Claims 9-19 is also merely a matter that would easily be conceived of by a person skilled in the art.</p>			Novelty (N)	Claims <u>1-19</u>	YES		Claims _____	NO	Inventive step (IS)	Claims _____	YES		Claims <u>1-19</u>	NO	Industrial applicability (IA)	Claims <u>1-19</u>	YES		Claims _____	NO
Novelty (N)	Claims <u>1-19</u>	YES																		
	Claims _____	NO																		
Inventive step (IS)	Claims _____	YES																		
	Claims <u>1-19</u>	NO																		
Industrial applicability (IA)	Claims <u>1-19</u>	YES																		
	Claims _____	NO																		